UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,190	06/27/2007	Yiyou Chen	GC846-US	7097

7590 02/17/2010

Elena E. Quertermous
DANISCO US INC., GENENCOR DIVISION
925 Page Mill Road
Palo Alto, CA 94304

EXAMINER	
SZPERKA, MICHAEL EDWARD	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
02/17/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,190	CHEN, YIYOU	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *1-12 and 22-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response received December 3, 2009 is acknowledged.

Claims 1-28 are pending.

Applicant's election without traverse of group II, claims 13-21, as they read on camelid antibodies in the reply filed on December 3, 2009 is acknowledged.

Claims 1-12 and 22-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 3, 2009.

Claims 13-21 are under examination in this office action.

Specification

2. The title and abstract are objected to for not clearly specifying the subject matter claimed in the instant application. Specifically, both refer to methods, whereas the elected invention is directed to products. Appropriate amendment of the title and abstract to better reflect that which has been instantly claimed is suggested.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 13-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin (US Patent 5,482,040).

Martin disclosed the tumor glycoprotein antigen TAG-72, as well as antibodies to this antigen and methods of detecting this antigen (see entire document, particularly the abstract). Thus, Martin discloses the isolated antigen TAG-72.

It should be noted that the independent claim recites "an *antigen* or antigen binder" and thus all claims under examination are product claims. Thus, any of the steps set forth in such product claims are properly construed as product-by-process limitations. As per MPEP 2113, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Note that in the instant case, none of the process steps change the physical form of the claimed *antigen*, specifically TAG-72.

Therefore, the prior art anticipates the claimed invention.

5. Claims 13-18, 20, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamers et al. (WO 94/25591 A1).

Hamers et al. disclose the isolation of camelid heavy chain antibodies (V_HH) by recombinant methodologies (see entire document, particularly the abstract). They further disclose fusion proteins comprising V_HH fused to reporter molecules (see particularly pages 17, 22, 25, and 26). One exemplary reporter molecule to be used in such fusion molecules is the enzyme glucose oxidase (see particularly Example 7). The

instant specification discloses on page 9 that BLA is a genus of enzymes, of which glucose oxidase is a member. As such, Hamers et al. disclose fusion proteins comprising a camelid V_HH fused to a BLA reporter molecule.

As was stated above, the independent claim recites "an antigen or antigen binder" and thus all claims under examination are product claims. Note that V_HH are "antigen binders". Thus, any of the steps set forth in such product claims, such as isolation via RT-PCR or ELISA measurements, are properly construed as product-by-process limitations. As per MPEP 2113, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Note that in the instant case, none of the process steps change the physical form of the claimed V_HH-reporter other than claim 18, which indicates that the reporter must be a BLA. However, as discussed above, glucose oxidase is a BLA as defined by the instant specification. Additionally, the language of the independent claim is such that it is not clear that the claimed V_HH need actually bind a tumor antigen, such as those identified in claim 14.

Therefore, the prior art anticipates the claimed invention.

6. Claims 13-21 are rejected under 35 U.S.C. 102(a and e) as being anticipated by Muyldermans et al. (WO 03/055527 A2).

Muyldermans et al. disclose CEA-specific camelid V_HH conjugated to beta-lactamase for use in treating tumors (see entire document, particularly the abstract, pages 4, 6, and 7, and examples 1-4). These constructs are disclosed as comprising superior in vivo characteristics including reduces immunogenicity and superior killing as compared to other immunoconjugates (see particularly page 3).

It should be noted that the instant claims are constructed using product by process type limitations. As per MPEP 2113, "[E]ven though product-by-process claims

are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Therefore, the prior art anticipates the claimed invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kadow et al. (US Patent 5,773,435) in view of Hamers et al. (WO 94/25591 A1).

Kadow et al disclose antibodies and antigen binding fragments thereof conjugated to the enzyme beta lactamase for various diagnostic and therapeutic uses (see entire document, particularly the abstract). Such conjugates can be made in a multitude of ways, including as fusion proteins via recombinant molecular biology technology (see particularly column 8). These conjugates differ from the structure of the instant claimed invention in that Kadow et al. do not disclose V_HH antibodies from camelid animals.

Hamers et al. disclose that V_HH isolated from camelid animals can be used in fusion proteins comprising various enzymes, and that V_HH do not comprise a light chain and thus offer the advantage of increased ease of production of antibody fragments in both prokaryotic and eukaryotic hosts as compared to producing Fab' and single chain Fv fragments (see entire document, particularly pages 12, 15, 17, and 22).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use V_HH in the antibody-beta-lactamase fusion constructs of Kadow et al. Motivation to do so comes from the numerous advantages of V_HH as compared to other conventional antibody antigen fragments, such as ease of purification in both eukaryotic and prokaryotic hosts as disclosed by Hamers et al. Note that claim 19 requires the use of a nitrocefin assay. Nitrocefin is a substrate of beta-lactamase that changes color upon cleavage by the enzyme. Thus, the product claimed in claim 19 reasonably must comprise a V_HH joined to beta-lactamase. As per MPEP 2113, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

9. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kadow et al. (US Patent 5,773,435) in view of Hamers et al. (WO 94/25591 A1) as applied to claim 19 above, and further in view of Schlom et al. (US Patent 5,512,443).

The inventions rendered obvious by the disclosures of Kadow et al. and Hamers et al. have been discussed above and differ from the instant claimed invention in that the antibodies rendered obvious are not indicated as binding the tumor antigen TAG-72.

Schlom et al. disclose the use of antibody fragments specific for the tumor antigen TAG-72 to treat human cancers, such antibodies further being disclosed as being coupled to therapeutic drugs and toxins (see entire document, particularly the abstract and columns 2, 7, 11, and 12).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to make V_HH-beta-lactamase fusion constructs specific for the TAG-72 antigen. Motivation to do so comes from the fact Kadow et al. discloses that conjugates comprising beta-lactamase can be used to treat any cancer, while

Schlom et al. indicate the desirability of directing antibodies to bind the TAG-72 antigen for cancer therapy.

Claim Objections

10. Claims 15-21 are objected to because the independent claim from which they depend recites a product, not a method. As such, claims 15-21 are all product claims. Appropriate amendment of the claims to acknowledge this fact is suggested.

Claim 18 is also objected to for the recitation of "BLA". This term appears to be an abbreviation which stands for a large genus of enzymes as per page 9 of the instant specification. Thus, in the interest of clarity and readability, all abbreviations should be spelled out in full upon their first recitation in any chain of dependency, with further dependent claims then using the abbreviation for the sake of brevity. Appropriate correction is suggested.

11. No claims are allowable.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is (571)272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka, Ph.D.
Primary Examiner
Art Unit 1644

/Michael Szperka/
Primary Examiner, Art Unit 1644